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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,021	02/06/2004	Orn Adalsteinsson	ARK-153US1	7718

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EXAMINER
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CHEN, STACY BROWN

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 05/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/774,021

Applicant(s)

ADALSTEINSSON ET AL.

Examiner

Stacy B. Chen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 46-59 is/are pending in the application.
- 4a) Of the above claim(s) 52-59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 46-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 2/6/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_



### **DETAILED ACTION**

1. Applicant's election with traverse of Group I, claims 46-51, in the reply filed on March 4, 2005 is acknowledged. The traversal is on the ground(s) that a thorough search for Group I also includes a search for the subject matter of Groups II and III. Applicant argues that a search for the use of the product would reveal literature relevant to the subject matter of Groups II and III. Applicant also argues that the inventions are closely related. This is not found persuasive because a search for a composition comprising glucosamine and an egg will not necessarily reveal literature that speaks to Applicant's methods. The inventions are classified separately (product from processes of use). A search for all inventions would be a serious burden, for reasons of record. The requirement is still deemed proper and is therefore made FINAL.
2. Claims 46-51 are under examination. Claims 52-59 are withdrawn from consideration because they are drawn to non-elected inventions.

### ***Specification***

3. The specification, page 1, is objected to because the status of parent application, USSN 09/656,712, has not been updated to reflect that USSN 09/656,712 is now US Patent 6,706,267.

### ***Oath/Declaration***

4. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02. The oath or declaration is defective because non-initialed and/or

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non-dated alterations have been made to the oath or declaration, specifically, the docket number.

See 37 CFR 1.52(c).

### ***Claim Objections***

5. Claim 49 is objected to for reciting, "HCl" instead of "HCl". Correction is required.

### ***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 46 and 48-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- The claims are drawn to a composition comprising glucosamine and an active egg fraction. The specification does not clearly define what an "active" egg fraction is, other than an egg yolk in claim 47 (not rejected). Also undefined is "partially purified anti-inflammatory fraction of the egg", which is from the yolk. What component is the active fraction or the anti-inflammatory fraction? The examples show a whole egg, yet the "active" fraction and "anti-inflammatory fraction" is not identified. Is Applicant referring to IgY? The metes and bounds of the "active" egg fraction cannot be determined without a definition. Correction is required to overcome this rejection.
- Claim 49 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

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regards as the invention. Claim 49 recites an improper Markush group. The claim should read, "selected from the group consisting of". Correction is required.

***Declaration of Mr. Leslie A. Confer under 37 CFR 1.132***

7. The opinion declaration of Mr. Leslie A. Confer under 37 CFR 1.132 filed March 29, 2004, is acknowledged. Each point of the declaration will be addressed in turn.

- Points 1-3 identify Mr. Leslie A. Confer and his experience in the fields of immunology, biology, microbiology and biochemistry.
- Points 4 and 5 detail the four non-existent microorganisms that were mistyped in the original disclosure.
  - In response, the Office is persuaded that the non-existent microorganisms in the original disclosure are products of transcriptional errors.
- Point 6 discloses the species, simulans, dysenteriae, epidermidis and vulgaris, and all of their possible genuses.
- Points 7 and 8 propose four microorganisms to replace the original four non-existent microorganisms in the original disclosure. Point 9 reasons that the proposed four microorganisms are the logical and consistent choice when considering the PL-100 bacterial listing. The other species besides the four proposed species are not pathogenic to humans or animals, and therefore are not consistent with the PL-100 bacterial listing of J. P. Euzeby's *The List of Bacterial Names with Standing in Nomenclature*, available from <http://www.bacteria.net>, copyright 1997-2003. Mr. Confer, in Points 10 and 11, offers his opinion that the original disclosure's errors resulted from transcriptional errors,

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and that the bacterial genus and species names proposed as corrections are the only true and valid genus and species replacements that would apply.

- The proposed genus and species corrections have been considered with respect to the alternative genus/species, and the corrections will not be considered new matter. It is noted that J. P. Euzeby's 2111-page publication, *The List of Bacterial Names with Standing in Nomenclature*, is more directly accessible from <http://www.bacterio.cict.fr/> than <http://www.bacteria.net>. The same amendment was permitted in a 312 amendment in parent application 09/656,712, now US Patent 6,706,267.

***Declaration of Dr. Subramanian Iyer (inventor) under 37 CFR 1.132***

8. The opinion declaration of Dr. Subramanian Iyer under 37 CFR 1.132 filed March 29, 2004, is acknowledged. Each point of the declaration will be addressed in turn.

- Points 1-3 identify Dr. Iyer and his experience in the fields of immunology, biology and biochemistry.
- Points 4 and 6 address the figure attached as Exhibit A, which depicts the effects of the whole egg, egg yolk and highly purified fraction of egg (3kD) in the Rat Type II collagen induced arthritis model. The egg was obtained from a hyperimmune chicken egg produced according to Example 1 of the specification. The model shows that the whole egg, egg yolk and 3kD fraction begins to inhibit inflammation starting at day 13. These results demonstrate that all three egg embodiments are able to inhibit inflammation.

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- In response, the data show that the whole egg, egg yolk and 3kD fraction inhibit inflammation starting from around day 13.
- Points 7-9, Dr. Iyer offers his opinion on the meaning of the data presented in Exhibit A. The synergistic effect of glucosamine with whole egg is expected between glucosamine and egg yolk or the 3kD fraction, or any other immune-inducing fraction of the egg. Dr. Iyer believes that other skilled artisans would draw the same conclusions.
- In response, the synergistic effect that Dr. Iyer refers to is not represented in the data of Exhibit A. Exhibit A shows only the response to eggs and does not include glucosamine. Therefore, conclusions about synergism with glucosamine cannot be determined from the data of Exhibit A. While Dr. Iyer holds that one of skill in the art would extrapolate synergism between various egg components and glucosamine based on the activity of eggs (fractions thereof) absent glucosamine, the Office does not agree with this opinion because there is no evidence to support Dr. Iyer's conclusion. Evidence of synergism requires that both components of the synergistic activity be used simultaneously.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claim 46 is rejected under 35 U.S.C. 102(b) as being anticipated by Kondo *et al.* (US 4,367,309, "Kondo"). Claim 46 is drawn to a composition comprising glucosamine and an active egg fraction. (The specification does not clearly define "active" egg fraction, so the egg fraction is interpreted as any egg fraction with no specific activity required.) Kondo discloses a composition comprising a glycoprotein (conjugated protein) containing a carbohydrate. Specifically, the glycoprotein is egg albumin and the carbohydrate is glucosamine (column 2, lines 5-22). Therefore, lacking a clear definition of "active egg fraction", the claim is anticipated by Kondo.

### ***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 46-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adalsteinsson *et al.* (WO 99/36077, "Adalsteinsson") in view of Yue (US 6,251,863). The claims are drawn to a composition comprising glucosamine and an active egg fraction. (The specification does not clearly define "active" egg fraction, so the egg fraction is interpreted as any egg fraction with no specific activity required.) The egg fraction is egg yolk, or a partially purified anti-inflammatory fraction of the yolk. (The specification does not clearly define "anti-inflammatory fraction of the yolk, so the anti-inflammatory fraction is interpreted as any egg fraction of a yolk with anti-inflammatory activity.) The glucosamine is glucosamine HCl or



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glucosamine sulfate, in the amount of approximately 10 mg to 5 grams. The immunogenic vaccine that is used to hyperimmunize the chicken from which the egg is taken, comprises various immunogens selected from a list in claim 51.

Adalsteinsson teaches a composition comprising an egg or fraction thereof, wherein the egg has been hyperimmunized with at least one antigen (abstract). The antigen is from bacteria, viruses, protozoa, fungi and cellular antigens (Adalsteinsson, claim 8). The composition also contains NSAIDs or DMARDs (claim 23). Adalsteinsson fails to teach glucosamine as part of the composition.

However, Yue teaches that glucosamine sulfate has been shown to treat joint disease. Yue suggests that it is a preferable treatment for the inflammation and pain of the joints instead of NSAIDs (col. 5, lines 19-26). It would have been obvious to substitute the glucosamine sulfate of Yue for Adalsteinsson's NSAIDs or DMARDs. One would have been motivated by Yue's teaching that glucosamine sulfate is a preferable treatment for inflammation instead of NSAIDs. One of ordinary skill in the art would have had a reasonable expectation of success that glucosamine would work in Adalsteinsson's method because Adalsteinsson uses an anti-inflammatory drug, and glucosamine is a known anti-inflammatory treatment, evidenced by Yue. Determining the dosages of glucosamine and egg would have been well within the ability of one of ordinary skill. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time of the invention.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

### ***Double Patenting***

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 46-51 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,706,267 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are a species encompassed by the instantly claimed genus. The genus claims are drawn to a composition comprising glucosamine and an egg (any part thereof that induces an immune response). The patented claims are drawn to a composition comprising glucosamine and a whole egg. Therefore, the patented species claims render the instant genus claims obvious.

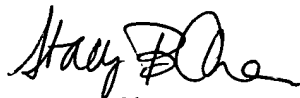
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***Conclusion***


12. No claim is allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



Stacy B. Chen  
April 29, 2005



JAMES HOUSEL 5/2/05  
SUPERVISORY PATENT EXAMINER  
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